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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,975	08/26/2003	Dusan Miljkovic	100700.0016US1	4147

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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
04/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,975	MILJKOVIC, DUSAN	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Claims 12-17 in the reply filed on 6/8/2007 is acknowledged. As indicated in the prior Office Action, the restriction between Groups I and II was withdrawn. As such, claims 1-17 are directed to the elected invention with claims 18-20 withdrawn as directed to the non-elected invention.

Claim Objections

Claims 2-11 are objected to because of the following informalities: Claim 1 on which the claims are 2-11 are directly or indirectly dependent is directed to a kit comprising a dietary supplement and instruction, as such, the preamble to claims 2-11 should be directed to the kit not to a dietary supplement. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant does not indicate where in the Specification where the term "kit" is supported by the written description and based on a review of the Specification and claims as originally filed, there does not appear to be a written description of said term. As such, there is

no evidence that the Applicant had possession of the claimed invention at the time the Application was filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miljkovic (US Pat. 5,962,049) in view of Naghii et al. (Abstract), Nielsen, Volpe et al. (Abstract) and FDA Talk Paper (9/23/1997).

Miljkovic discloses a nutritional supplement containing a carbohydrate-boron complex which is charged neutralized with calcium or magnesium, where the carbohydrate ligand can be fructose or have a boron-ligand association constant is at least 5000 where the ligand is mannose, mannitol, sorbose or sorbitol (Claims 4-6, 11,12). It is disclosed that Beta-fructofuranose has a boron association constant of 6,000 (Column 3, lines 60-68, Column 4, lines 1-38). It is disclosed that boron offers significant benefits with respect to bone and joint health and that the optimum daily of intake is about 2-3 mg/day (Column 1, lines 23,24,35,36). It is disclosed that the sugar-boron compounds can be included in pharmaceutical preparations, including with suitable excipients, binders, carriers and other compounds as known in the pharmaceutical arts, including vitamin pills and other forms of supplements, with the dosage providing about 0.01 mg/day/dose to about 10 mg/day/dose or more of boron (Column 5, lines 13-22, Column 6, lines 1-5).

Naghii et al. disclose that supplementation of 10 mg of boron per day for 4 weeks significantly increased plasma estradiol concentrations and there was a trend for plasma testosterone levels to be increased (Abstract).

Neilsen disclose an experiment in which patients were fed a boron-low diet for 63 days and then supplemented with 3 mg/day boron for 49 days and that when compared serum 25 hydroxycholecalciferol was lower in the depletion period compared to the repletion period (Page 59). It is disclosed that the reason for estrogen therapy is to prevent calcium and bone loss which can lead to osteoporosis (page 62).

Volpe et al. disclose that the role of boron in bone metabolism and increasing bone density is most likely to be associated with interactions with other minerals and vitamins, such as calcium, magnesium and vitamin D (Abstract).

The FDA Talk Paper (9/23/1997) discloses that products containing ingredients such as vitamins and minerals are required to have labels identifying them as dietary supplements, providing appropriate serving size information on 14 nutrients, when present at significant levels, including calcium, other vitamins and minerals if they are added or part of a nutritional claim on the label and dietary ingredients for which no Reference Daily Intakes have been established (Pg. 1 of 2).

The prior art discloses a carbohydrate-boron complex having a ligand affinity of greater than 2500, including a calcium or magnesium (fructose, mannose, mannitol, sorbose, or sorbitol) boron complex and that boron is important in bone and joint health. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose combining with Vitamin D, formulation as a tablet or capsule, or a method of increasing steroid

concentration in a human with the carbohydrate-boron complex. The prior art amply suggests the same as the prior art discloses that boron supplementation decreases bone loss, increases serum levels of estradiol, testosterone and 25-hydroxy cholecalciferol, that estrogen therapy decrease calcium and bone loss, that boron's effect on bone metabolism is likely due to interactions with calcium, magnesium and vitamin D and that the carbohydrate-boron complex can be in various pharmaceutical forms, including vitamin pills. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the carbohydrate-boron complex would be effective in increasing steroid concentration in humans, that increasing serum estradiol would increase bone density, that boron's effect on bone metabolism would be facilitated by the addition of calcium, magnesium and vitamin D and that the dietary supplement can be in any form desired, including pills and mixtures with suitable excipients, binders and carriers and other compounds included as known in the pharmaceutical arts.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Supreme Court in *KSR International Co. v. Teleflex Inc.,* held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

As such, the Applicant's argument as to teach, suggestion or motivation is without merit.

The Applicant argues that the claims require that the kit includes an instruction and a boron-ligand association constant of at least 2,500. The claims do not define any structural limitation with respect to the kit and no where in the Specification is the term defined. As such, the Examiner reads the term "kit" which is part of the preamble as not providing any patentable distinction between the prior art and the claimed invention. See e.g. *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It is unclear how the Applicant can assert that element with respect to the boron-ligand association constant of at least 2,500 is not taught or suggested by any combination of the cited references and subsequently acknowledge in the next paragraph that the '049 patent teaches the same that the prior art discloses boron-carbohydrate compositions. In any case, the '049 patent

does disclose and/or suggest boron-carbohydrate ligand compositions where the boron-ligand association constant is at least 2500, as indicated above.

With respect to the instructions, the prior above disclose and/or suggest the presence of instructions as to amount and use for promoting bone health and increasing steroid levels. As indicated above, boron supplementation is disclosed in the prior art to promote bone health and increase steroid concentrations of estradiol and testosterone. Further, products containing vitamins and minerals are required to provide a list of ingredients, serving size and identify vitamins and minerals that are part of a nutritional claim on the label. As such, one of ordinary skill in the art would be motivated to provide the same in conjunction with the dietary supplement in order to comply with the FDA rules. In any case, there is no new and unobvious functional relationship between the printed matter, i.e the instructions, and the substrate, i.e. the dietary supplement, in that the instructions merely provide information as to the use of the dietary supplement, which dietary supplement and use for bone health and increasing steroid concentrations are suggested by the prior art. See e.g. *In re Ngai*, 70 USPQ2d 1862 (Fed. Cir. 2004).

The Applicant argues that the amount of 2-3 mg/day of boron as promoting bone health refer to immediately available boron formulations. However, the Applicant provides no evidence that carbohydrate-boron compositions of the '049 patent would not promote bone health. The 3 mg/day and the 10 mg/day amounts disclosed in Nielsen and Naghii, respectively, are well within the range disclosed the '049 patent, i.e. 0.01 mg/day/dose to about 10 mg/day/dose or more of boron. Further, there is nothing in '049 that patent that indicates that very high boron dosages are required for bone health. The '049 patent only indicates that the

optimum daily intake of boron in humans appears to be about 2-3 mg/day and that boron offers significant benefits with respect to bone health. It does not state that a supplement must provide 2-3 mg/day of boron or that boron supplementation is limited to 2-3 mg/day. In any case, the claims do not set for any specific dosage amount or range with respect to the daily amount or dose. As such, the Applicant's arguments with respect to amounts and dosage fail to support the Applicant's conclusion that complexes in which boron is tightly bound, i.e. an association constant of at least 2,500, is clearly not contemplated to be employed in bone health aspects.

The Applicant indicates that the same considerations apply in view of Naghii, as the reference expressly teaches administration of boron at a daily dose of 10 mg/day. However, as indicated above, the claims do not require any specific amount or range and 10 mg/day is clearly within the dosage range for the boron-carbohydrate ligand compositions disclosed in the '049 Patent.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
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April 21, 2008

/Johann R. Richter/
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